UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY
CAMDEN VICINAGE

IN RE: VALSARTAN, LOSARTAN, AND IRBESARTAN PRODUCTS LIABILITY LITIGATION **This Document Relates to the TPP Trial Subclasses**	MDL No. 2875 Honorable Robert B. Kugler, District Court Judge

TPP TRIAL DEFENDANTS' MEMORANDUM OF LAW IN SUPPORT OF MOTIONS IN LIMINE[1]

[1] These Motions in Limine concern the claims designated in the Court's Case Management Order No. 32 (the "TPP Trial Claims"), specifically, the claims of Plaintiff MSP Recovery Claims, Series LLC, as class representative of TPP Breach of Express Warranty subclass b, TPP Fraud subclass c, and TPP State Consumer Protection Laws subclass a, against the TPP Trial Defendants. (ECF 2343 at 1-2.) Accordingly, this motion is limited to the TPP Trial Claims, and is presented without waiver of any arguments for exclusion of any evidence from trial with respect to any other claims asserted by any plaintiff as to any defendants in this multidistrict litigation.

Defendants Zhejiang Huahai Pharmaceutical Co., Ltd.; Huahai U.S., Inc.; Prinston Pharmaceutical Inc.; Solco Healthcare U.S., LLC; Teva Pharmaceuticals USA, Inc.; Teva Pharmaceutical Industries Ltd.; Actavis LLC; Actavis Pharma, Inc.; Torrent Pharmaceuticals Ltd.; and Torrent Pharma, Inc. (collectively, the "TPP Trial Defendants" or "defendants"), by and through their undersigned counsel, respectfully move to exclude certain evidence from trial of this matter.

STANDARD

The most fundamental rule of evidence is that of relevance: evidence is only admissible if it has a "tendency to make the existence of any fact that is of consequence to the determination of the action more probable or less probable." Fed. R. Evid. 401; Fed. R. Evid. 402. Moreover, even relevant evidence should be excluded if its probative value is substantially outweighed by a danger of . . . unfair prejudice, confusing the issues, misleading the jury, undue delay, wasting time, or needlessly presenting cumulative evidence." Fed. R. Evid. 403. Several categories of evidence should be excluded under these and other evidentiary standards.

ARGUMENT

1. EVIDENCE, TESTIMONY, REFERENCE, OR ARGUMENT THAT THE JURY SHOULD SEND A MESSAGE TO THE TPP TRIAL DEFENDANTS

Defendants anticipate that plaintiffs' counsel may attempt, through argument to the jury and examination of witnesses, to persuade jurors that they should send a

message to the defendants with their jury award. Such evidence should be excluded under Fed. R. Evid. 403, as numerous courts have held. *See, e.g.*, *Webb v. Cent. Fla. Invs., Inc.*, No. 5:18-cv-01304, 2021 WL 852139, at *1 (S.D. W. Va. Mar. 5, 2021) (granting motion to exclude "send a message" arguments because they are "irrelevant and highly prejudicial"). "Send a message" arguments are inherently prejudicial because they urge the jury to render a verdict based on "passion and prejudice" instead of the law and evidence. *White v. Ford Motor Co.*, 312 F.3d 998, 1020 (9th Cir. 2002); *see also Johnson v. BLC Lexington SNF, LLC*, No. 5:19-064-DCR, 2020 WL 7322718, at *9, *16 (E.D. Ky. Dec. 11, 2020) (similar); *BE & K Constr. Co. v. United Bhd. of Carpenters & Joiners of Am.*, 90 F.3d 1318, 1331 (8th Cir. 1996) (similar). This is true even in cases where plaintiffs seek punitive damages. *See Hassebrock v. Air & Liquid Sys. Corp.*, No. C14-1835RSM, 2016 WL 4496917, at *8 (W.D. Wash. Apr. 11, 2016) (plaintiff could not invite the jury to "send a message" even though plaintiff sought punitive damages because such a statement "would be unfairly prejudicial"). A plaintiff may not use punitive damages as "a platform to expose, and punish, the perceived deficiencies of [defendants'] operations throughout the country." *State Farm Mut. Auto. Ins. Co. v. Campbell*, 538 U.S. 408, 419 (2003). Accordingly, such evidence should be excluded.

2. REGULATORY ISSUES UNRELATED TO THE PROCESSES ALLEGED TO HAVE CAUSED FORMATION OF NITROSAMINES

The Court should preclude plaintiffs from introducing evidence or argument

related to FDA warning letters, Establishment Inspection Reports ("EIRs"), Form 483s, FDA communications with defendants or other regulatory-related communications unrelated to the specific manufacturing processes and chemical reactions that allegedly resulted in the presence of NDMA or NDEA in the at-issue valsartan active pharmaceutical ingredient ("API") and valsartan finished-dose ("FD") products. This includes communications involving facilities where products other than the API or FD products at issue are or were manufactured. EIRs are issued by the FDA after an inspection is closed. EIRs also include Form 483s, which "are a snapshot of the firm's compliance status at the time of the FDA inspection and include significant observations made during the inspection." (Rep. of Akhilesh Nagaich, Ph.D. ¶ 60, Dec. 22, 2022 (ECF 2301-3).) "Form 483 is not considered a final corrective action by the agency but instead is meant to alert the company to harmful conditions." *In re Tylenol (Acetaminophen) Mktg., Sales Pracs. & Prods. Liab. Litig.*, 181 F. Supp. 3d 278, 297 (E.D. Pa. 2016). EIRs, Form 483s, and similar regulatory communications unrelated to the processes at issue are irrelevant, unfairly prejudicial, and constitute inadmissible character evidence.

Courts routinely exclude regulatory materials, including warning letters and Form 483s, related to other products as irrelevant and inappropriate distractions. *See Sadler v. Advanced Bionics, Inc.*, No. 3:11-CV-00450-H, 2013 WL 1311148, at *1 (W.D. Ky. Mar. 26, 2013) (concluding that contents of a "Form 483 are not relevant

to any issue presently before the [c]ourt" since it concerned products "which are not at issue in this case"); *Dalbotten v. C. R. Bard, Inc.*, No. 1:20-cv-00034-SPW, 2023 WL 1778793, at *1 (D. Mont. Feb. 6, 2023) (excluding FDA warning letters about defendant's other IVC filters not at issue in the case because its "relevance is substantially outweighed by its risk of confusing the jury as to the issues"); *In re Bard IVC Filters Prods. Liab. Litig.*, No. CV-16-00474-PHX-DGC, 2018 WL 1109554, at *4 (D. Ariz. Mar. 1, 2018) (granting motion *in limine* with respect to topics in FDA's Warning Letter that are "not relevant to this case"). The same principle applies here. Plaintiffs should not be allowed to raise regulatory concerns that do not implicate ZHP's development and use of the Zinc Chloride and TEA with quenching processes to manufacture valsartan API, or the aspects of those processes that unexpectedly led to the creation of nitrosamines.

At best, such evidence would confuse jurors, and at worst, it would be used to improperly suggest that defendants have a propensity for violating their regulatory obligations. In either case, it should be excluded as prejudicial and as improper character evidence. *See Hall v. Bos. Sci. Corp.*, No. 2:12-cv-08186, 2015 WL 856786, at *7 (S.D. W. Va. Feb. 27, 2015) (granting motion *in limine* to "exclude a 2006 corporate warning and FDA 483 letters concerning cardiac devices"; "[t]his evidence has little to no probative value for the plaintiff's claims regarding pelvic mesh . . . and has significant potential to unfairly prejudice [defendant], confuse the

issues, or mislead [the] jury"); *In re Davol, Inc./C.R. Bard, Inc., Polypropylene Hernia Mesh Prods. Liab. Litig.*, No. 2:18-cv-1509, 2021 WL 2643109, at *7 (S.D. Ohio June 28, 2021) ("Evidence of FDA inspections . . . about other devices demonstrating non-compliance with FDA regulations is inadmissible character evidence under Federal Rule of Evidence 404 if offered to prove . . . nonconformity with FDA regulations."). For example:

ZHP. The DMF Complete Response Letter that the FDA faxed to ZHP on June 6, 2018, related to ZHP's drug master file ("DMF") for valsartan, but none of the comments addressed: (1) the steps of the manufacturing process during which plaintiffs claim the NDMA or NDEA formed; (2) the use of DMF solvent or Sodium Nitrite in the processes; or (3) the need to be alert for potential nitrosamine formation. (*See generally* PRINSTON00019155 (Ex. 1 to Cert. of Jessica Davidson ("Davidson Cert.")).) Instead, the letter addressed, *inter alia*, (1) potential issues with the use of dibromohydantoin and azobisiobutyrontirile to manufacture "OTBN"; (2) a byproduct of that same reaction; and (3) the 2018 implementation of USP <232>, which requires manufacturers to provide a risk assessment for elemental impurities in their API. (*See generally id.*)

Teva. The FDA Form 483s sent to Teva and Teva's predecessor company following routine FDA inspections of Teva's Malta facility in April 2014 and February 2017 do not include any observations related to valsartan products or the

processes at issue in this case. Indeed, plaintiffs have never alleged that the impurities at issue arose during the finished dose manufacturing process. Instead, the four observations during those inspections relate to: (1) HEPA filters; (2) compression of tablets using the wrong tooling; (3) updating written criteria for stability testing; and (4) validation of manual cleaning activities. (*See* TEVA-MDL2875-00015292 (Davidson Cert. Ex. 2); TEVA-MDL2875-00828468 (Davidson Cert. Ex. 3).) None of these observations or subsequent correspondence about them is relevant to any issue in this case.

Torrent. Most of the EIR issued by the FDA to Torrent on July 18, 2017, based on its inspection of Torrent's facilities between April 17-28, 2017, had nothing to do with the VCDs.[2] (TORRENT-MDL2875-00004362 (Davidson Cert. Ex. 4).) Moreover, the EIR contained four observations in the form of Form 483s, none of which is relevant. The 2017 EIR clearly lists the "[f]inished products covered" during the inspection, which do not include VCDs. (TORRENT-MDL2875-00004362 at 1.) In fact, the 2017 EIR notes that VCDs were covered during the FDA's ***previous*** inspection of Torrent on May 16-20, 2016. (TORRENT-MDL2875-00004362 at 2.) Thus, introduction of the 2017 EIR and Form 483s would confuse

[2] The section titled "Voluntary Corrections" on pages 55-56 of the 2017 EIR should not be excluded because it addresses Torrent's response to "Inspectional Observations" made by the FDA during its May 20, 2016 inspection, which did relate to VCDs. (TORRENT-MDL2875-00004362 at 2, 55-56.)

and mislead the jury into believing that the FDA's observations with respect to ***non***-VCD products also apply to Torrent's manufacture of VCDs. Further, plaintiffs have made clear that they intend to use the 2017 EIR and the Form 483s as improper character evidence by citing to these documents as proof of "Torrent's Admissions Regarding [non-compliance with] cGMP." (ECF 2560 at 13 & ¶ 58.)

All of this evidence is irrelevant and highly prejudicial and should be excluded from trial.

3. LITIGATION CONDUCT AND DISCOVERY DISPUTES

The Court should exclude any evidence or argument regarding the parties' litigation conduct, including references to document productions, discovery disputes, litigation holds, sanctions motions or confidentiality designations. (*See, e.g.*, Pls.' Designations of Apr. 20, 2021 Dep. of Min Li, Ph.D. 160:8-14, 160:16, 160:21-161:4, 161:7 (Davidson Cert. Ex. 5).)

First, evidence and argument concerning litigation conduct and discovery disputes are not relevant to the merits of this case. The central issues at trial will be whether defendants breached warranties or engaged in fraud by selling medications with alleged impurities. Evidence regarding discovery disputes between the parties is not probative of any of those issues. *See, e.g.*, *Tutein v. Ford Motor Co.*, 67 V.I. 139, 142 (Super. Ct. 2016) (excluding "evidence or argument concerning discovery disputes between parties in this matter" because it "does not have any tendency to

make a fact more or less probable than it would be without the evidence").[3]

Second, evidence regarding discovery agreements and disputes would also be unfairly prejudicial and unnecessarily confusing under Rule 403. *See Thompson v. Glenmede Tr. Co.*, No. 92-5233, 1996 U.S. Dist. LEXIS 13672, at *5-7 (E.D. Pa. Sept. 16, 1996) (excluding evidence related to discovery disputes due to risk that "[r]ather than focus on the issues in the case, the jury may instead be misled by the irrelevant side issues of the discovery process"). Indeed, courts have expressly held that "any relevance" of discovery agreements and disputes "is substantially outweighed by the risk of confusing jurors who presumably have little or no knowledge or understanding of discovery procedures." *Nance*, 2013 WL 1337155, at *3-4; *Tutein*, 67 V.I. at 142-43 (similar). Accordingly, the Court should prohibit plaintiffs from making any reference to litigation conduct or disputes.

4. UNNECESSARY REFERENCES TO CANCER-RELATED TERMS

Defendants seek to bar plaintiffs from excessively and gratuitously using cancer-related terms (e.g., "genotoxic," "carcinogenic," "carcinogen," "cancer," or

[3] *See also, e.g.*, *Sw. La. Convention & Visitors Bureau v. Emps. Mut. Cas. Co.*, No. 06-2006, 2009 WL 1787680, at *2 (W.D. La. June 22, 2009) (excluding "correspondence of counsel related to discovery disputes, motions to compel and/or other discovery issues" and any reference to documents allegedly not produced by defendants); *Knight v. Boehringer Ingelheim Pharms., Inc.*, 323 F. Supp. 3d 837, 861-62 (S.D. W. Va. 2018) (similar); *Nance v. Innovasis, Inc.*, No. Civ-11-432-D, 2013 WL 1337155, at *3-4 (W.D. Okla. Mar. 29, 2013) (similar); *Walton v. Bridgestone/Firestone, Inc.*, No. CV-05-3027-PHX-ROS, 2009 WL 2778441, at *9 (D. Ariz. Jan. 16, 2009) (similar).

"cancer-causing") when questioning witnesses on matters for which those terms are unnecessary. *See, e.g., United States v. Sena*, No. 19-CR-01432, 2021 WL 4129247, at *2 (D.N.M. Sept. 9, 2021) (finding "that the prejudice resulting from the repeated use of the term 'victim' at trial" to refer to the alleged victim "substantially outweighs the probative value of the term"); *United States v. Garcia-Limon*, No. CR 21-0032 RB, 2022 WL 3334498, at *1 (E.D. Okla. May 16, 2022) (same).

This is not a theoretical concern. Plaintiffs' counsel used these terms at least 251 times during Dr. Jaiswal's deposition, 75 times during Peng Dong's deposition, 95 times during Eric Gu's deposition, and 86 times during Dawn Chitty's deposition. There is nothing probative to be gained from using "carcinogenic" or "genotoxic" as routine modifiers or adjectives when questioning about non-scientific topics. Rather, the only conceivable purpose behind such tactics is to unfairly prejudice defendants and inflame the jury. *See Carter v. Hewitt*, 617 F.2d 961, 972 (3d Cir. 1980) ("Evidence is unfairly prejudicial . . . if it 'appeals to the jury's sympathies, arouses its sense of horror, provokes its instinct to punish,' or otherwise 'may cause a jury to base its decision on something other than the established propositions in the case'") (citation omitted); *see also, e.g., United States v. Joetzki*, 952 F.2d 1090, 1094 (9th Cir. 1991) (evidence is "unfairly prejudicial . . . if it has an undue tendency to suggest a decision on an improper basis such as emotion or character"); *United States v. D'Elia*, No. 3:CR-06-191, 2007 WL 2458487, at *5 (M.D. Pa. Aug. 24,

2007) (excluding evidence where there was "a substantial danger . . . that . . . evidence may provoke a jury's 'instinct to punish'") (citations omitted); *O'Connor v. City of El Segundo*, No. 20-311-DMG (PLAx), 2021 WL 4798649, at *3 (C.D. Cal. June 22, 2021) (excluding evidence that may lead jury to "choose to punish [d]efendants" for unrelated matter). Accordingly, the Court should strictly limit any evidence or argument regarding cancer and associated words to questioning for which those terms are necessary (i.e., questions related to general causation or the alleged risks of the impurities).

5. EVIDENCE OR ARGUMENT BASED ON A "REPTILE THEORY"

As described in the book "Reptile: The 2009 Manual of the Plaintiff's Revolution," there is a growing practice among plaintiffs' lawyers to appeal to the "reptilian" part of a juror's brain that houses basic survival instincts for themselves and the human species. In particular, the goal of reptilian strategies is to incite "jurors to decide a lawsuit 'based upon fear, generated by plaintiff[s'] counsel, that a verdict in favor of the defendant will harm the safety of the community, and, thus, the juror.'" *Brooks v. Caterpillar Glob. Mining Am., LLC*, No. 4:14CV-00022-JHM, 2017 WL 3401476, at *8 (W.D. Ky. Aug. 8, 2017) (citations omitted). Such arguments are similar to "Golden Rule," "send a message" and "conscience of the community" arguments and are thus inadmissible for the same reasons. *Id.* at *1-2; *see also id.* at *9 (excluding "any argument . . . that attempts to urge the jury to

render a verdict against [d]efendant on the basis of fear for the safety of the community or fear for the safety of the jury and their families"); *Elkins v. Automatic Data Processing, Inc.*, No. EDCV 21-606 JGB KKx, 2023 WL 7354621, at *7 (C.D. Cal. Apr. 19, 2023) (precluding reptilian arguments because they "deflect the jury from their task").

Plaintiffs' litigation history strongly suggests that they will pursue this prejudicial trial strategy. On the first page of their summary judgment motion, plaintiffs argue that "[t]his case presents a disturbing window into a ***clear and present danger to the United States drug supply***." (ECF 2569-1 at 1 (emphasis added).) *See Lee v. Dennison*, No. 2:19-cv-01332-KJD-NJK, 2023 WL 221339, at *1-2 (D. Nev. Jan. 17, 2023) (precluding reptilian arguments couching "allegations of liability in terms of safety rather than standard of care") (citation omitted). They also portray defendants as bad actors that allegedly "elevated their pursuit of market share and profit to an ***unsafe and reprehensible level***" and "abrogated their ***fundamental obligations to protect the safety of the intended patient population***." (ECF 2569-1 at 1 (emphases added).) Putting aside that plaintiffs' assertions are foreclosed by the FDA's own pronouncements, there is absolutely no probative value to such emotional, reptilian appeals, and defendants will be substantially prejudiced if such arguments are made to the jury. Fed. R. Evid. 403. Fed. R. Evid. 403.

6. EVIDENCE OR ARGUMENT SUGGESTING THAT DEFENDANTS MISLED THE FDA OR COMMITTED FRAUD ON THE FDA

Throughout these proceedings, plaintiffs and their experts have repeatedly alleged that defendants somehow defrauded the FDA with regard to their VCDs. For example, plaintiffs have claimed that defendants misrepresented to the FDA the purported impurities and genotoxic risk associated with their VCDs in their DMFs and ANDAs.[4] Plaintiffs have also suggested that both ZHP and Teva failed to timely disclose to the FDA the alleged presence of nitrosamines in their valsartan.[5] The Court should preclude plaintiffs from improperly arguing and presenting evidence suggesting that defendants somehow misled the FDA or committed fraud on the FDA because such a theory is preempted by federal law, is irrelevant to plaintiffs' claims, and its introduction would be unfairly prejudicial and confusing to the jury.

First, evidence or argument that defendants misrepresented information to—or withheld information from—the FDA is irrelevant. Fed. R. Evid. 401, 402. In *Buckman Co. v. Plaintiffs' Legal Committee*, 531 U.S. 341, 350-51 (2001), the Supreme Court held that state-law claims based on a theory that a plaintiff's injuries

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[4] (Pls.' SUMF re ZHP ¶¶ 126-134 (ECF 2569-3); Rep. of Susan Bain ("Bain Rep.") at 51, Oct. 31, 2022 (ECF 2884-3); Pls.' SUMF re Torrent ¶¶ 35-36, 60 (ECF 2560); Pls.' SUMF re Teva ¶¶ 54, 73 (ECF 2566); Rep. of Philip Russ ("Russ Rep.") ¶ 97, Oct. 31, 2022 (ECF 2303-2).)

[5] (Pls.' SUMF re ZHP ¶ 41.5 (ECF 2569-3); Bain Rep. at 49, 62; Pls.' SUMF re Teva ¶¶ 74-76 (ECF 2566); Russ Rep. ¶ 123.)

are the result of a pharmaceutical defendant's failure to provide certain information to the FDA are preempted by federal law. *Buckman* made clear that the adequacy of regulatory submissions to the FDA is an issue that can be determined by the FDA alone, and may not be considered by juries applying state laws. *Id.* at 349 n.4 (citing 21 U.S.C. § 337(a)). This Court has expressly acknowledged that any "Fraud-on-the-FDA" claim in this case would be preempted by *Buckman*. (ECF 675 at 12.)

As courts applying *Buckman* have made clear, the preemption principles that underlie the Supreme Court's decision necessarily render fraud-on-the-FDA evidence or arguments irrelevant and inadmissible. *See, e.g.*, *In re Trasylol Prods. Liab. Litig.*, 709 F. Supp. 2d 1323, 1338, 1346 (S.D. Fla. 2010) (similar); *Hines v. Wyeth*, No. 2:04-0690, 2011 WL 2680842, at *7 (S.D. W. Va. July 8, 2011) (similar); *In re Seroquel Prods. Liab. Litig.*, No. 6:06-md-1769-Orl-22DAB, 2009 WL 3806436, at *4-5 (M.D. Fla. July 20, 2009) (similar).[6] Accordingly, plaintiffs may not use their warranty, fraud, or consumer protection claims to advance arguments that defendants misled the FDA or present any evidence suggesting that defendants

[6] *See also Swank v. Zimmer, Inc.*, No. 03-CV-60-B, 2004 WL 5254312, at *2 (D. Wyo. Apr. 20, 2004) (excluding "evidence that [d]efendant misled the FDA" based on *Buckman*); *In re Bextra & Celebrex Mktg., Sales Pracs. & Prod. Liab. Litig.*, No. 06-2145 CRB, 2008 WL 8140112, at *1 (N.D. Cal. Apr. 30, 2008) ("exclud[ing] evidence that [the defendant] provided inadequate information to the FDA") (capitalization altered); *Bouchard v. Am. Home Prods. Corp.*, 213 F. Supp. 2d 802, 812 (N.D. Ohio 2002) (similar).

misrepresented information to the FDA or withheld information from that agency.

Second, any evidence or argument that the TPP Trial Defendants defrauded the FDA would confuse the jury and unfairly prejudice jurors against defendants. Fed. R. Evid. 403; *Bouchard*, 213 F. Supp. 2d at 812 ("Exclusion of . . . evidence [suggesting that the FDA was misled] may be necessary to prevent confusion of the jury as to the nature of [the plaintiff's] claims . . . ."). Evidence on this subject would mislead and confuse jurors into thinking that because defendants supposedly misrepresented information to the FDA or withheld information from that agency, they must have committed fraud against the TPP subclass members. For all of these reasons, the evidence should be excluded.

7. EVIDENCE OR ARGUMENT CONCERNING CORPORATE INTENT, MOTIVES AND ETHICS

The Court should also exclude expert evidence or testimony pertaining to defendants' overall corporate intent, motives and ethics.

No expert witness in this case is qualified, or has a reliable basis, to testify about defendants' alleged intent or motives, including any suggestion that defendants' actions were motivated by the desire to save money or increase profits. Moreover, such testimony would amount to inadmissible speculation and invade the province of the jury. *See DePaepe v. Gen. Motors Corp.*, 141 F.3d 715, 720 (7th Cir. 1998) (noting that it was error to allow expert testimony in a product liability case that the company failed to add a safety feature to "save money" because the expert

"lacked any scientific basis for an opinion about . . . motives"); *Tunnell v. Ford Motor Co.*, 330 F. Supp. 2d 707, 728-29 (W.D. Va. 2004) (expert may not testify on company's "knowledge or motivation"); *In re Trasylol Prods. Liab. Litig.*, 709 F. Supp. 2d 1323, 1338, 1346 (S.D. Fla. 2010) (excluding regulatory expert's testimony on intent, knowledge, and motivation; "courts have held that the question of (corporate) intent or motive is a classic jury question and not one for experts"); *Hines v. Wyeth*, No. 2:04-0690, 2011 WL 2680842, at *7 (S.D. W. Va. July 8, 2011) ("Inasmuch as [the witness] has no knowledge concerning defendants' state of mind or intent, the court would be hard pressed to allow her to opine at trial on defendants' motives . . . ."); *In re Seroquel*, 2009 WL 3806436, at *4-5 (excluding expert opinions about a pharmaceutical company's ethics, motives and intentions).

Finally, testimony as to any supposed motives behind Teva and Torrent's quality activities is doubly inadmissible because there is no evidence that they benefitted financially from the process change instituted by ZHP or that Torrent's use of a single API supplier impacted Torrent's motivations regarding cGMP compliance. Thus, any testimony regarding Teva or Torrent's motives would be both speculative and irrelevant.

8. EVIDENCE OF STATEMENTS OR ACTIONS BY REGULATORY AGENCIES OUTSIDE THE UNITED STATES

Defendants anticipate that plaintiffs may reference or introduce actions or statements of foreign regulatory agencies, particularly the European Medicines

Agency ("EMA") and the European Directorate for the Quality of Medicines & HealthCare ("EDQM") following the detection of NDMA in ZHP valsartan API, including statements related to the purported carcinogenicity of NDMA and the regulatory limits set by these agencies for acceptable daily intake ("ADI") of NDMA in medications. For example, during the deposition of Teva corporate representative Raphael Nudelman, plaintiffs introduced and questioned Dr. Nudelman about a document entitled "Request for Information Relating to the EU Referral Under Article 31 of Directive 2001/83/EC for Medicines Containing Valsartan," dated August 10, 2018 (TEVA-MDL2875-00408015 (Davidson Cert. Ex. 6)), which contains a statement by the EDQM that "NDMA is a carcinogenic risk substance for which carcinogenicity data exists." (*See* Dep. of Raphael Nudelman, Ph.D., ERT ("Nudelman Dep.") 50:9-18; 205:7-11, Apr. 8, 2021 (Davidson Cert. Ex. 7).) Plaintiffs also questioned Dr. Nudelman regarding the levels of NDMA found in Teva's valsartan and compared them to the regulatory limits later set by the EDQM. (*See id.* 209:18-23 ("Q. So we've got the Teva which is .57 parts per million. We've got the FDA at .5 parts per million, and EDQM at .3 parts per million, right? A. Correct, as of September 6, 2018.").) The Court should exclude this evidence for multiple reasons.

First, courts have repeatedly recognized that evidence of foreign regulatory statements and actions is irrelevant to claims alleging violations of U.S. law. *See*,

e.g., *Deviner v. Electrolux Motor, AB*, 844 F.2d 769, 771 n.2, 773 (11th Cir. 1988) (citing district court's "desire to avoid confusing the jury with Swedish law and statistics," the court held that "Swedish [s]tandards are not relevant in a U.S. product liability case involving a saw sold in the U.S."); *In re Viagra Prods. Liab. Litig.*, 658 F. Supp. 2d 950, 965 (D. Minn. 2009) ("[A]ny discussion of foreign regulatory actions is irrelevant to the current litigation and should therefore be excluded."); *In re Seroquel Prods. Liab. Litig.*, No. 6:06-md-1769-Orl-22DAB, 2009 WL 223140, at *5-6 (M.D. Fla. Jan. 30, 2009) (excluding evidence which could only show "that a different regulatory authority, applying different standards in a different social and medical landscape, reached a conclusion different than the conclusion reached by the FDA under the U.S. system"). Such evidence is all the more irrelevant to the extent it postdates the initial valsartan recall in the United States. In fact, this Court held in its Macro Discovery Order that plaintiffs were not even entitled to ***discovery*** regarding "foreign regulatory documents sent or received regarding Valsartan or the Valsartan recall." (*See* Macro Discovery Order ¶ 6 (ECF 303).) It follows perforce that this evidence, which was not even relevant for purposes of discovery, cannot possibly satisfy the more restrictive standards of the Federal Rules of Evidence.

Second, "allowing the admission of evidence of foreign regulatory actions, in

a case that is governed by domestic law, would likely cause jury confusion."[7] *In re Baycol Prods. Litig.*, 532 F. Supp. 2d 1029, 1054 (D. Minn. 2007); *see also In re Seroquel*, 2009 WL 223140, at *6 ("[W]hatever minimal relevance the foreign regulatory actions might have is clearly overwhelmed by the likelihood of jury confusion."). Such jury confusion could prejudice the TPP Trial Defendants if jurors believe that Teva failed to comply with applicable foreign regulatory standards. (*See, e.g.*, Nudelman Dep. 209:18-23 (suggesting through examination that the levels of NDMA in Teva's VCDs did not comply with ADI limits later set by the EDQM).) Moreover, if such evidence were admitted, the TPP Trial Defendants would be forced to present evidence and testimony explaining that the foreign regulatory bodies are subject to different laws from the FDA, may and do promulgate different regulatory standards from the FDA, and have no role in regulating the at-issue VCDs. This would result in mini-trials on irrelevant foreign regulatory statements and actions that would needlessly waste time. *See In re Seroquel Prods. Liab. Litig.*, 601 F. Supp. 2d 1313, 1318 (M.D. Fla. 2009) (barring evidence of foreign regulatory

[7] In *In re Tylenol*, 181 F. Supp. 3d at 307, the court admitted foreign labels as evidence of the defendants' notice of the risk at issue, while recognizing that such evidence "may require context of a foreign country's regulatory system in order to present them accurately, leading to a trial within a trial and undue delay." *Id.* Here, the United States was indisputably the first country in which VCDs were recalled due to the presence of NDMA; thus, any foreign regulatory actions are not relevant to notice.

actions; "[t]o admit evidence about the foreign regulators' actions" [would] result in a series of 'mini-trials' regarding the grounds for the decisions and the regulatory schemes of the three foreign countries involved. This would confuse the jury and waste everyone's time."). For all of these reasons, the Court should exclude evidence or argument related to statements or actions by the EMA, EDQM, or any other regulatory agency outside the United States.

9. EVIDENCE OR ARGUMENT RELATING TO THE ABSENCE OF CROSSCLAIMS OR TO EXISTENCE OF INDEMNIFICATION OBLIGATIONS AMONG DEFENDANTS

Defendants expect that plaintiffs will rely on the absence of cross-claims or the existence of indemnification obligations among the TPP Trial Defendants to draw negative inferences as to defendants' liability. Specifically, plaintiffs have expressed an intention to present to the jury letters from Torrent's and Teva's legal departments to ZHP related to settlement and indemnification, as well as potential agreements related to ZHP's indemnification for the costs of the recall. Plaintiffs should not be allowed to embark on this prejudicial side-show for multiple reasons.

First, any compromise offers and/or negotiations among the parties are "not admissible" under Rule 408 "either to prove or disprove the validity or amount of a disputed claim or to impeach by a prior inconsistent statement or a contradiction[.]" Fed. R. Evid. 408.

Second, defendants' indemnification agreements are further inadmissible under Rule 411, which bars evidence of liability insurance. *See* Fed. R. Evid. 411; *In re Gabapentin Patent Litig.*, MDL No. 1384, 2011 U.S. Dist. LEXIS 51130, at *32 n.33 (D.N.J. May 12, 2011) ("Indemnification agreements are treated like liability insurance under Rule 411.") (citing *In re Hanford Nuclear Reservation Litig.*, 534 F.3d 986, 1014 (9th Cir. 2008)).

Third, plaintiffs' claims relate to whether the TPPs suffered economic loss as a result of defendants' conduct. The potential liabilities of defendants against each other are irrelevant to that issue. Fed. R. Evid. 401; *see, e.g.*, *Goldenson v. Steffens*, No. 2:10-cv-00440-JAW, 2014 WL 3105033, at *10 (D. Me. July 7, 2014) (excluding "evidence of the indemnification agreement" because it "is not relevant to any trial issue").

Finally, even if indemnification obligations or the absence of cross-claims had some relevance (they do not), allowing such evidence would unfairly prejudice defendants, confuse the jury, and waste trial time. Fed. R. Evid. 403. A jury could place undue weight on the apportionment or shifting of liability among defendants and be misled into believing that cross-claims or indemnification claims are relevant or suggest wrongful conduct by any of the TPP Trial Defendants. *See*, *e.g.*, *Jones v. City of College Park*, No. 1:05-CV-1797-JTC, 2009 WL 10744201, at *1 (N.D. Ga. Aug. 31, 2009) (excluding indemnification evidence intended to be used as "an

admission of liability by the [defendant]" because the "minimal relevance such evidence has is outweighed by the likelihood that it may induce the jury to decide the case on something other than the merits"). For example, the jury may incorrectly interpret the absence of cross-claims as evidence that certain defendants admit responsibility for the conduct of other defendants, or the jury may mistakenly and impermissibly conclude that the existence of indemnification requests or agreements somehow shows prior knowledge of misconduct or admits liability. *See id.* Moreover, admitting such evidence would force the TPP Trial Defendants to explain what cross-claims and indemnification claims are and why they do not matter here. That would distract the jury and waste time on irrelevant issues. *Ballard v. DeJoy*, No. 2:20-cv-02679-MCS-E, 2021 WL 3811026, at *2 (C.D. Cal. June 2, 2021) (excluding "evidence [that] would risk unfair prejudice, confusing the jury, and wasting time by inviting mini-trials" on unrelated issues).

10. EVIDENCE OR REFERENCE TO INDIVIDUALS WHO USED VALSARTAN AND DEVELOPED CANCER OR CLAIM ECONOMIC LOSS

Defendants anticipate that plaintiffs may attempt to introduce testimony or argument involving individuals who used VCDs and later developed cancer, or to call consumers to testify about their individual VCD purchases and putative economic losses. Such evidence should be excluded because it is irrelevant, inflammatory, and would require mini-trials on the circumstances and causation of

each individual's cancer or each individual's VCD purchases.

First, any evidence of VCD users who developed cancer has no relevance to this case. This trial does not involve any personal injury claims by patients who took defendants' VCDs. Rather, the plaintiffs are third-party payors seeking economic loss damages. That certain individuals took VCDs and subsequently developed cancer is irrelevant to the TPP Plaintiffs' claims. The economic loss claims of individual consumers who purchased VCDs and may have subsequently regretted their decision are equally irrelevant to the question of whether the third-party payor class members have cognizable economic loss claims.

Second, evidence of individual consumers taking VCDs and subsequently developing cancer would unfairly prejudice defendants, create a substantial risk of juror confusion, and waste time. Fed. R. Evid. 403. If plaintiffs are permitted to present such evidence, it would give the false impression that plaintiffs are here to advocate for cancer patients, which risks confusing the jury as to who the plaintiffs in this case are, and also galvanizing the jury against defendants. Rather than deciding the economic loss claims on their merits, the jury could be incited to "punish" defendants for unrelated harms allegedly suffered by individual consumers and to unfairly sympathize with plaintiffs. *See, e.g.*, *D'Elia*, 2007 WL 2458487 at *5 (excluding evidence where there was "a substantial danger . . . that . . . evidence may provoke a jury's 'instinct to punish'") (citations omitted); *O'Connor* 2021 WL

4798649, at *3 (excluding evidence that may lead jury to "choose to punish [d]efendants" for unrelated matter). Likewise, presenting the testimony of individual consumers who purchased VCDs and assert economic losses would create the false and prejudicial impression that plaintiffs are advocating for the economic interests of individual consumers who purchased and took VCDs, rather than the third-party payor class members.

Such evidence would also waste trial time by requiring mini-trials on specific causation. Determining the cause of an individual's cancer involves an analysis of his or her medical and family history, lifestyle, genetic, and environmental factors. If plaintiffs are allowed to present evidence related to individual cancer cases, defendants will be forced to respond with evidence about those individuals' lifestyles, medical and family histories, exposure to occupational hazards, and other varied individualized evidence. This would result in irrelevant mini-trials that would distract jurors and the Court from the matters at issue.

11. REFERENCE OR TESTIMONY RELATED TO VALSARTAN SOLD OUTSIDE THE UNITED STATES AND API SUPPLIERS OTHER THAN ZHP

Defendants anticipate that plaintiffs may try to introduce evidence and argument related to Teva's products containing API manufactured by Mylan Laboratories Limited (the "Mylan products" or "Mylan API") or VCDs sold outside the United States. Such evidence should be excluded. Plaintiffs' trial claims arise

solely from purchases of finished-dose valsartan products containing API manufactured by Defendant ZHP and sold in the United States. Evidence of products manufactured using different API or sold outside of the United States is thus irrelevant to the claims and would unnecessarily—and significantly—expand the scope of trial.

Mylan Products/API. Teva manufactured VCDs containing Mylan API at a separate facility in a different country than the facility where ZHP API was used. Expert discovery has not been taken as to liability issues and defenses related to the Mylan API and the Mylan supply chain. And no Mylan witness can or will testify at this trial. Nonetheless, plaintiffs have indicated they will attempt to expand this trial by introducing evidence, argument, and expert criticisms related to Teva's decision to continue selling VCDs with Mylan API in the immediate aftermath of Teva's recall of VCDs made with ZHP API. That decision was made *after* Teva was notified of the potential impurity in ZHP's API and had placed all ZHP API on hold, and *before* Teva (or Mylan) received any notice that Mylan's API was affected by nitrosamines. Accordingly, none of the evidence plaintiffs state they intend to introduce as to Mylan products has any logical connection to Teva's conduct with respect to the VCDs made with ZHP API.

As background, upon learning from ZHP about the detection of an unspecified impurity in its valsartan API, Teva initially placed a hold on all valsartan finished-

dose product, regardless of API source, on June 21, 2018. (TEVA-MDL2875-00791611 (Davidson Cert. Ex. 8).) Teva later released its hold on products manufactured with Mylan API to avoid a valsartan shortage, based on evidence that Mylan's products did not follow the same process and would not lead to formation of NDMA. (Dep. of Claire Lyons ("Lyons Dep.") 304:18-305:12; 317:11-22, Apr. 27, 2021 (Davidson Cert. Ex. 9).) Later, it was discovered that some batches of Mylan products contained a separate nitrosamine impurity—NDEA—and Teva ultimately recalled products containing Mylan API as well. (TEVA-MDL2875-00731926, Teva Field Alert (Davidson Cert. Ex. 10).)

Plaintiffs intend to present criticisms by Philip Russ regarding Teva's release of Mylan products, such as, "Teva continued to sell finished dose valsartan with Mylan API without regard to cGMP requirements." (Russ Rep. ¶ 135.) Mr. Russ also opines that it "would be expected under cGMP that Teva perform an impact assessment to determine the potential for NDMA to be present in valsartan" from suppliers other than ZHP. (*Id.* ¶ 129.) But Mr. Russ did not review any Mylan documents before forming this opinion and could not answer basic questions about it at his deposition. (Dep. of Philip Russ 199:4-24, Jan. 5, 2023 (ECF 2303-3) ("Q. So you just don't know one way or the other whether the Mylan NDEA issue was caused by the same route of synthesis [as NDMA] or something different? . . . A. I don't have any opinion on that.").) In fact, Mr. Russ *acknowledges* in his report that

"[i]ssues relating to Mylan's valsartan API and Teva's sourcing from and oversight of Mylan **are not the subject of this report**." (Russ Rep. ¶ 24 (emphasis added).) Furthermore, the initial analysis criticized by Russ ultimately proved to be correct; Mylan's products did not follow the same process as ZHP's, and their products did not and could not form NDMA as a result of a similar chemical reaction to the one understood to occur in ZHP's synthetic route. Indeed, no Mylan products were ever found to contain NDMA above allowable limits. Accordingly, plaintiffs should not be permitted to introduce these admittedly irrelevant, incorrect opinions by Mr. Russ, or other evidence related to Teva's decision to continue selling products made with Mylan API following its recall of ZHP products. *See* Fed. R. Evid. 401; 402.

Permitting plaintiffs to introduce argument related to Teva's decision to release Mylan products would dramatically expand the scope of trial. For example, Teva would need to introduce testimony by its corporate witnesses explaining the decision to release Mylan API. (*See, e.g.*, Lyons Dep. 107:5-20; 304:18-20; 361:2-8.) Further, in order to respond to plaintiffs' unsupported and barely considered criticisms of Teva's decision to continue selling Mylan API VCDs, Teva would need to introduce evidence regarding Mylan's primary and tertiary API manufacturing process and the recall of Mylan products in order to demonstrate the differences in the Mylan and ZHP processes, the differences in how the impurity formed, the differences in the investigation, how Mylan performed the analysis Teva relied on

in deciding to release its hold on Mylan product, and so on. In short, admission of evidence related to Mylan API would necessitate a mini-trial related to Mylan API, an issue that was intended to be eliminated from this trial through the selection ***by plaintiffs*** of a class of plaintiffs that paid only for VCDs containing ZHP API. This would result in a significant waste of time that would undoubtedly confuse and frustrate the jury.

VCDs Sold Outside US. Evidence regarding VCDs sold outside the United States and facilities that did not manufacture product for the United States is likewise irrelevant to any issue to be decided in this trial. In fact, this Court ruled in its November 25, 2019, Macro Discovery Order, that discovery was limited to "Valsartan sold in the United States." (Macro Discovery Order ¶ 2 (ECF 303) (emphasis added).) Nonetheless, defendants anticipate that plaintiffs will try to introduce evidence from markets outside the U.S. to attempt to show that defendants failed to comply with (irrelevant) regulations, had (non-nitrosamine) impurities in other batches of Valsartan products, or for other irrelevant and improper purposes. For example, plaintiffs may seek to present emails from Teva Japan about unknown peaks to suggest that non-nitrosamine peaks in valsartan sold in Japan should have somehow led Teva to investigate and identify the presence of NDMA in US product. (*See* TEVA-MDL2875-00514869 (Davidson Cert. Ex. 11); Dep. of Anthony R. Binsol 205:22-209:19, May 13, 2021 (Davidson Cert. Ex. 12) ("I would point out

that [the email chain] speaks of hydrolyzed calpronium chloride, which is not a nitrosamine.").) Plaintiffs may also try to delve into Teva's testing capabilities worldwide, to suggest that R&D testing methods not approved for valsartan or any product actually marketed should have been employed to conduct unvalidated investigatory testing of valsartan API. (*See*, *e.g.*, Dep. of Daniel Barreto 216:5-23, Apr. 14, 2021 (Davidson Cert. Ex. 13).) Because the defendants market and sell their products throughout the world, it is impossible to speculate how plaintiffs may try to use evidence related to VCDs sold outside of the United States. Regardless, as with evidence related to VCDs made with Mylan API, permitting evidence of VCDs not sold in the U.S. and facilities not involved in manufacturing product for the United States would needlessly expand the trial. Accordingly, the evidence should be excluded.

CONCLUSION

WHEREFORE, the TPP Trial Defendants respectfully request that the Court issue an order excluding the evidence described herein from trial.

Dated: February 16, 2024

Respectfully submitted,

By: */s/ Jessica Davidson*
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CERTIFICATE OF SERVICE

I HEREBY CERTIFY that on February 16, 2024, I electronically filed the foregoing with the Clerk of the Court by using the CM/ECF system which will send a notice of electronic filing to all CM/ECF participants in this matter.

/s/ *Jessica Davidson*
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